REMARKS

The Office Action mailed May 24, 2010 (hereinafter, "Office Action") has been reviewed and the Examiner's comments considered. Claims 30-47 are pending in this application, with claims 34-39 withdrawn from consideration. No amendments are made herein.

Drawings

The drawings 7A-C stand objected to under 37 CFR 1.83(a) for failing to show every feature of the invention specified in the claims, including the built-in valve. The Office asserts that the built-in valve 206 with a slit is shown in non-elected FIGS. 4A-E but not in the elected FIGS. 7A-C. (Office Action, p. 2.) Applicant respectfully disagrees as FIGS. 4A-E illustrate only a single embodiment of the recited built-in valve, of which FIGS. 7A-C illustrate a representative embodiment.

According to 37 CFR 1.83, the drawings "must show every feature of the invention specified in the claims. However, conventional features disclosed in the description and claims, where their detailed illustration is not essential for a proper understanding of the invention, should be illustrated in the drawings in the form of a graphical drawing symbol or a labeled representation."

As described, FIGS. 7A-7D illustrate "another embodiment of the multifunction adaptor of the present invention [including] a tapered connector housing and removable syringe adaptor assembly. … It should be appreciated that the tapered connector housing and removable syringe adaptor could be design features for any of the embodiments described herein." (Instant Specification, ¶ [0047].) Referring to the actual drawings, FIGS. 7A-7D include a graphical drawing symbol, similar to the valve of FIG. 1, to depict the possible valves as described by the incorporated embodiments. As shown below by the comparison of FIG. 1 to FIG. 7A, the valve of FIG. 7A includes "a built-in valve longitudinally fixed with respect to the connector having a closed proximal end with a slit and an open distal end," as recited by independent claim 30.

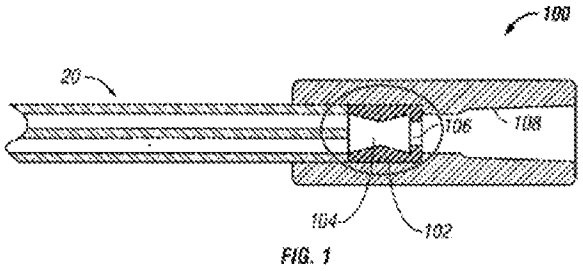

FIG. 1

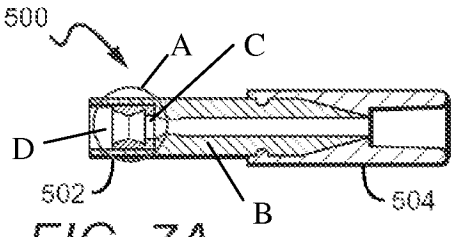

FIG. 7A

Referring to FIG. 1, above, connector 100 includes a valve 102 including a slit 106. (Instant Specification , ¶ [0041].) The valve 102 is built into the connector 100 and is longitudinally fixed with respect to the connector. In comparison, FIG. 7A illustrates a valve similarly depicted, although not specifically labeled with drawing numbers. Accordingly, FIG. 7A also depicts a built-in valve A longitudinally fixed with respect to the connector B having a closed proximal end with a slit C and an open distal end D. Moreover, with respect to the general graphical depiction of the valve, along with the description to any of the described embodiment within the specification, the valve of FIGS. 4A-E, admittedly containing the recited features, is also reasonably within the proper understanding of FIGS. 7A-C, as described.

In view of the above, Applicant submits that the drawings illustrate an exemplary embodiment of the recited built-in valve. By reference to the graphical valve symbol and the description to the design features of any of the described embodiments, the drawings adequately provide sufficient structural detail for a proper understanding of the disclosed invention, including an exemplary embodiment of the "built-in valve longitudinally fixed with respect to the connector." Accordingly, Applicant respectfully requests withdrawal of the outstanding objection to the drawings.

Claim Rejections – 35 USC § 112

Claim 30 stands rejected under 35 USC 112, first paragraph, as failing to comply with the written description requirement. Applicant respectfully traverses the rejection.

The Office asserts that the present specification or elected species of Figures 7A-7C does not show the limitation of "a built-in valve having a closed proximal end with a slit and an open distal end," as recited by independent claim 30. (Office Action, p. 3.) The Office notes that the limitation is only shown in Figures 4A-E, which is drawn to a non-elected species. (Office Action, p. 3.) Applicant respectfully traverses this rejection, as the valve of Figures 4A-E is but one exemplary embodiment of the recited built-in valve.

As shown above, with respect to the drawing objection, FIG. 7A illustrates an exemplary built-in valve having a closed proximal end with a slit and an open distal end. Accordingly, Applicant respectfully requests withdrawal of the rejection under 35 USC 112, first paragraph.

Claim Rejections 35 USC § 103

Claims 30-32, 40, and 43-45 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over USPN 6,402,723 to Lampropoulos et al. (hereinafter, "Lampropoulos") in view of USPN 4,874,377 to Newgard et al. (hereinafter, "Newgard"). Claims 33 and 41 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Lampropoulos in view of Newgard, and further in view of USPN 4,256,116 to Shoor (hereinafter, "Shoor"). Claims 42 and 46-47 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Lampropoulos in view of Newgard and further in view of USPN 6,921,396 to Wilson et al (hereinafter, "Wilson"). Applicant respectfully traverses these rejections.

The Office asserts that Lampropoulos discloses a connector including an engagement feature 29 configured to connect an end of an instrument 114 to the connector. (Office Action, p. 3.) Applicant respectfully disagrees as the combination fails to disclose the recited "proximal portion of the passageway including an engagement feature configured to connect an end of an instrument to the connector."

Lampropoulos shows and describes a hemostasis valve apparatus including a valve body and a resiliently deformable seal disposed within the valve body. (Lampropoulos, Abstract.) "Luer connector 29 is an example of coupling means coupled to plunger 16 for coupling a fluid delivery

means for delivering fluid in fluid communication with passageway 26. Connector 29 preferably extends integrally from the proximal end of plunger 16. Other examples of such coupling means include threads, grooves, detents, spring loaded coupling mechanisms, pins, and a variety of other connectors configured to connect plunger 16 to a fluid delivery means." (Lampropoulos, col. 5:13-21.)

Newgard shows and describes a self-occluding cannula assembly having a connector hub. (Newgard, Abstract.) "A female Luer connector 44 is formed on the proximal end of the hub 38. ... A Luer-lock flange 46 extends peripherally around the proximal end of the female Luer connector 44 so as to accommodate an appropriately threaded locking fixture which may optionally be formed on the corresponding male connector." (Newgard, col. 6:40-51.)

As shown and described, the asserted engagement feature 29 of Lampropoulos is a luer connector on an external surface of the plunger. The passageway of the asserted connector, as shown, is conversely uniform. Accordingly, the passageway of the asserted connector does not include an engagement feature as recited by independent claim 30. Newgard does not supply the missing feature, as it similarly describes a flange on an external surface of the connector. Therefore, the asserted combination fails to show and describe the limitations of independent claim 30.

The Office further asserts that Lampropoulos discloses a connector including a valve 80 and 14 longitudinally fixed with respect to the connector. (Office Action, pp. 3-4.) The Office admits that Lampropoulos does not disclose that the built-in valve has a closed proximal end with a slit and an open distal end, but uses the valve 48 of Newgard to supply the admittedly missing features. (Office Action, p. 4.) The Office asserts that it would have been obvious at the time of the invention to modify the device of Lampropoulos with a slit valve, as taught by Newgard, in order to prevent the fluid back flow therethrough. Applicant respectfully disagrees, as the asserted combination fails to disclose the recited "built-in valve longitudinally fixed with respect to the connector having a closed proximal end with a slit and an open distal end."

As set forth in MPEP § 2143(A), "[t]he rationale to support a conclusion that the claim would have been obvious is that all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination yielded nothing more than predictable results to one of ordinary skill in the art." (MPEP § 2143(A), emphasis added.) Further, as set forth in MPEP § 2143.01, under *KSR*, "[i]f the proposed modification or combination of prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious." (*KSR*, 550 U.S. 398, 82 USPQ2d 1385 (2007).)

Under the guidelines of combining references, in order to combine the teachings of Lampropoulos with that of Newgard, the valve of Lampropoulos is either (1) replaced with the valve of Newgard, or (2) modified to include the features of the closed proximal end with a slit and open distal end of the Newgard valve. However, either combination fails to support a *prima facie* case of obviousness as (1) the replaced valve of Lampropoulos no longer teaches a valve "longitudinally fixed with respect to the connector" or (2) the modification changes the principle of operation of the Lampropoulos valve such that it is unsatisfactory for its intended purpose.

Lampropoulos shows and describes a hemostasis valve apparatus including a valve body 12, a first resiliently deformable seal 14 disposed within valve body 12 and a plunger 16 movably coupled to valve body 12. (Lampropoulos, col. 4:56-60.) With respect to the seal 14, Lampropoulos describes:

> With reference now to FIG. 2, first seal 14 comprises a tubular seal. First seal 14 has an interior surface defining a longitudinal flow path 30 extending therethrough. Flow path 30 communicates with lumen 18 of valve body 12 when first seal 14 is in an open position. An elongated instrument, such as a catheter or guide wire, can be disposed through path 30 of seal 14. First seal 14 assumes a normally open position when not subjected to a compressive force, but responds to a compressive force to

> reduce the size of flow path 30. When 14 moves radially inward to form a progressively tighter seal around a catheter or guide wire that is disposed in seal 14. The resiliently deformable seal 14 seats within a compression chamber 32 of valve body 14.

(Lampropoulos, col. 5:37-50.)

Newgard shows and describes a self-occluding cannula assembly with a self-actuating occluding means to prevent back flow of body fluids from the cannula. (Newgard, Abstract.) As shown in FIG. 4, the occluding means shifts between a "non-occluded" configuration and an "occluded" configuration by the lateral movement of the occluding means, as described as follows:

> So long as the obturator 48 remains in its relaxed position the dilator projection 52 does not exert sufficient proximally directed pressure on the obturator 48 to cause dilation of the aperture 64. It is only when the obturator 48 is depressed distally into its annular seating groove 50 that the conical dilator projection 52 will interact with the obturator 48 to cause dilation and opening of the aperture 64.

(Newgard, col. 7:50-60.)

As shown and described, if the Lampropoulos valve is replaced by the Newgard valve, the combination results in the valve no longer being longitudinally fixed with respect to the connector. Instead, in order to actuate the modified Lampropoulos device, the valve would longitudinally shift as described by Newgard in order to open against the dilator projection. Accordingly, the combination fails to teach a "built-in valve longitudinally fixed with respect to the connector," as recited by independent claim 30.

Alternatively, if the Lampropoulos valve is modified so that the valve includes just the closed proximal slit and the open distal end of Newgard, the resulting combination impermissibly changes the principal of operation of the Lampropoulos device. Lampropoulos describes a tubular

seal in a normally open configuration. The seal is contained within a compression chamber in order to progressively reduce the diameter of the tubular seal to create a tighter seal around an inserted guide wire or catheter. Conversely, the configuration of Newgard including the asserted closed proximal end with a slit and open distal end is in a normally closed position that is opened by the lateral movement of the seal against a dilator. Modifying the valve of Lampropoulos with a slit would result in the valve of Lampropoulos always being in a closed position. The slit contained within the compression chamber of Lampropoulos would be in a normally closed position and when actuated by the compression chamber would be in a tighter closed position. Accordingly, the modification changes the principal of operation of the Lampropoulos valve from a normally open valve to a normally closed valve. Moreover, as the modified seal permanently occludes the hemostasis valve lumen, the resulting device is also unsatisfactory for its intended purpose.

In view of the above, Applicant respectfully submits that a *prima facie* case of obviousness has not been established at least because all of the claim limitations are not taught or suggested by the cited combination of references (MPEP § 2143), and further because the combination of Lampropoulos and Newgard cannot properly be combined. Accordingly, for at least these reasons, independent claim 30 is patentable over the cited combination. Claims 31-32, 40, and 43-45 are patentable because they depend from a patentable independent claim, and also because they recite features not shown or described by the cited art. Therefore, Applicant requests favorable reconsideration and withdrawal of the rejections under 35 U.S.C. § 103.

Regarding the rejections of dependent claims 33, 41-42, and 46-47 in view of the combinations set forth above, Applicant submits that each claim depends from patentable independent claim 30 in view of the above. Therefore, without conceding the propriety of the asserted combinations, Applicant requests favorable reconsideration and withdrawal of the rejections of these claims under 35 U.S.C. § 103.

Double Patenting

Claims 30-33 and 40-47 stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 of USPN 7,578,803 ("the '803 patent"). Applicant respectfully traverses this rejection.

Applicant respectfully submits that instant claim 30 is patentably distinct from the patented independent claims. Patented claim 1 of the '803 patent recites "the inner surface of the wall narrowing from the valve proximal end to a valve mid portion and enlarging from the valve mid portion to the valve distal end" which is not present in instant claim 30, nor any of the remaining dependent claims. Patented claims 8 and 15 both recite first and second engagement means or features for connecting first and second ends of the tunneler which is not present in instant claim 30, nor any of the remaining dependent claims. Accordingly, instant claim 30 and dependent claims 31-33, and 40-47 are patentably distinct from patented claims 1-15 of the '803 patent. Applicant notes that dominant claims (i.e., broad claims in the absence of statutory or non-statutory grounds) by themselves, as noted in the MPEP at § 804, are inappropriate to support an obviousness-type double patenting rejection.

Accordingly, the pending claims are distinct from those of the '803 patent for at least this reason, and Applicant requests favorable reconsideration and withdrawal of the double patenting rejection.

Conclusion

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

It is noted that the remarks herein do not constitute, nor are they intended to be, an exhaustive enumeration of the distinctions between the cited references and the claimed invention.

Rather, the distinctions identified and discussed herein are presented solely by way of example. Consistent with the foregoing, the discussion herein should not be construed to prejudice or foreclose future consideration by Applicant of additional or alternative distinctions between the claims of the present application and the references cited by the Examiner and/or the merits of additional or alternative arguments.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 50-2191, under Order No. 101672.0019P from which the undersigned is authorized to draw.

Dated: August 24, 2010

Respectfully submitted,

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